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To: Examiner Kinsey White, N.E. - TC/AU: 1648
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Tabitha A. Trice
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ATTACHMENT/S: DRAFT SET OF PROPOSED REVISED CLAIMS

In re Patent Application of:

HELLSTROM et al
Serial No. 10/578,848
Filed: May 10, 2006
For: METHODS AND MEANS RELATING TO HEPATITIS B INFECTION

Dear Examiner Kinsey White:

With reference to our telephone discussion of earlier, attached is a copy of the proposed revised claims for your review.

I look forward to speaking with you on Thursday.

Best regards.

Mary J. Wilson

CONFIDENTIALITY NOTE

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1. (Currently Amended) A method of ~~predicting~~ determining whether an individual having hepatitis B virus (HBV) infection will respond to interferon alpha (IFN α) treatment, the method comprising:

- i) obtaining a pre-treatment sample from said HBV-infected individual,
- ii) analyzing said pre-treatment sample for determining the presence or absence of antibodies reactive with a preS1 peptide consisting of the sequence of residues 94-117 (SEQ ID NO:1) in a pre-treatment sample obtained from the individual, and;
predicting from wherein the presence of said antibodies in said pre-treatment sample indicates that said individual will respond to said treatment or predicting from and the absence of said antibodies in said pre-treatment sample indicates that said individual will not respond to said treatment.

2.-3. (Cancelled).

4. (Previously Presented) A method according to claim 1 wherein the individual has chronic HBV infection.

5. (Previously Presented) A method according to claim 1 wherein the individual is HBeAg positive.

6. (Previously Presented) A method according to claim 1 wherein the individual is HBeAg negative.

7. (Currently Amended) A method according to claim 1 wherein in step (ii), said pre-treatment sample is analyzed for the presence or absence of the antibodies are IgG or IgM antibodies reactive with said preS1 peptide.
8. (Previously Presented) A method according to claim 1 wherein the pre-treatment sample is a blood, serum or plasma sample.
9. (Currently Amended) A method according to claim 1 wherein step (ii) comprises comprising:
contacting the pre-treatment sample with a preS1 peptide consisting of the sequence of residues 94-117 (SEQ ID NO:1) and;
detecting the presence or absence of binding of determining binding of said antibodies to said preS1 peptide.
10. (Currently Amended) A method according to claim 9 wherein the preS1 peptide comprises a detectable label.
11. (Currently Amended) A method according to claim 9 wherein said preS1 peptide is immobilised.
12. (Previously Presented) A method according to claim 9 wherein said binding is detected with a labelled secondary antibody.

13.-19. (Cancelled).

20. (Currently Amended) A method of treating a ~~hepatitis B~~ an HBV infection in an individual identified as being responsive to IFN α comprising:

- i) obtaining a pre-treatment sample from an HBV-infected individual,
- ii) analyzing said pre-treatment sample for determining the presence or absence of antibodies reactive with a preS1 peptide consisting of the sequence of residues 94-117 (SEQ ID NO:1) in a pre-treatment sample obtained from the individual,
predicting from wherein the presence of said antibodies in said pre-treatment sample indicates that said individual will respond to ~~interferon alpha (IFN α)~~ IFN α treatment, and;
- administering IFN α to said individual identified as being responsive to IFN α .

21. (Cancelled).

22. (Currently Amended) A method according to claim 20 further comprising administering wherein a corticosteroid to said individual identified as being responsive to IFN α is administered to the individual.

23. (Cancelled).